



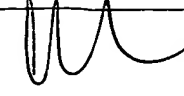
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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR              | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------------------|---------------------|------------------|
| 09/708,617  | 11/09/2000  | Wilhelmus Joseph Leonardus Suyker | DVME-1005US         | 1725             |
| 21302   | 7590        | 09/09/2004                        | EXAMINER            |                  |
| KNOBLE, YOSHIDA & DUNLEAVY<br>EIGHT PENN CENTER<br>SUITE 1350, 1628 JOHN F KENNEDY BLVD<br>PHILADELPHIA, PA 19103 |             |                                   | ODLAND, KATHRYN P   |                  |
|   |             |                                   | ART UNIT            | PAPER NUMBER     |
|   |             |                                   | 3743                |                  |

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |  |  |
|------------------------------|-------------------------------|--|--|
| <b>Office Action Summary</b> | Application No.<br>09/708,617 | Applicant(s)<br>SUYKER ET AL.  |  |
|                              | Examiner<br>Kathryn Odland    | Art Unit<br>3743   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 36, 37 and 40-64 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 58-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 37 and 40-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment dated April 21, 2004. Claims 1-10, 36, 37 and 40-64 are pending. Claims 36 and 58-64 are withdrawn from consideration. Amended claim 36 is now directed to a non-elected species (Species 2); therefore, it has been withdrawn from consideration.

### ***Specification***

The amendments to the specification and title are acknowledged.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1 and 37 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 37, 40-43 and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaster et al. in US Patent No. 5,366,462.

Regarding claim 1, Kaster et al. disclose a connector (12) for mechanically connecting hollow structures having an annular member (such as that generally at 46) of deformable material having a center line and a main plane and permanently deformable by expansion via plastic deformation from a first size in a starting position in

which the connector is delivered to a desired anastomosis site to a second, larger size in a joining position in which the connector connects the hollow structures, as recited throughout the specification and seen in the figures; joining elements (such as 43, 44) circumferentially spaced about the annular member (generally at 46) for joining abutting walls of hollow structures together, the joining elements having staple-like elements (tip) which are permanently deformable form a starting position in which the connector is delivered to a desired anastomosis site to a joining position in which the staple-like elements engage the hollow structures to thereby cause the connector to connect the hollow structures where each staple-like elements is attached to the annular member and has at least two staple portions extending from the location of attachment between each staple-like element and the annular member to free ends of each staple portion, at least part of each staple portion being tapered in a direction corresponding to a direction from the location of attachment between each staple-like elements and the annular member towards the free ends of the staple portion, as seen in figure 9. It is noted, that the centerline and main plane have not been defined with respect to any axis.

Regarding claim 2, Kaster et al. disclose that as applied to claim 1, as well as, each staple portion that tapers to at least a lesser radial thickness, as seen in figure 9.

Regarding claim 3, Kaster et al. disclose that as applied to claim 1, as well as, a centerline of each of the staple-like elements that is disposed substantially within a radial plane of the annular member, as seen in figures 8 and 10, for example.

Regarding claim 4, Kaster et al. disclose that as applied to claim 2, as well as, staple-like elements that are substantially straight in their starting positions, as seen in figure 8. "Starting position" is a broad recitation and could include manufacturing processes. Nonetheless, method steps do not hold patentable weight in apparatus claims.

Regarding claim 5, Kaster et al. disclose that as applied to claim 3, as well as, staple portions of the staple-like elements that have extreme tips, in the starting position, that are curved to approximate an anticipated curve of the tips resulting from the deformation of the staple like elements from the starting position to the joining position, as recited throughout and seen in the figures.

Regarding claim 6, Kaster et al. disclose that as applied to claim 1, as well as, a connector that is made from one piece of material, seen in the figures.

Regarding claim 7, Kaster et al. disclose that as applied to claim 1, as well as, staple portion of at least some of the staple-like elements that are configured differently on opposite sides of the point of attachment between the staple-like elements and the annular member, as seen in figure 21 via the taper.

Regarding claim 37, Kaster et al. disclose a connector for mechanically connecting hollow structures having an annular or tubular member (such as 46 and associated

components) of deformable material being adapted to be permanently deformed from a first size in a starting position in which the connector is delivered to a desired, to a second, larger size in a joining position in which the connector connects hollow structures; and joining elements (such as 43, 44) that are circumferentially spaced about the annular or tubular member for joining abutting walls of the hollow structures together, the joining elements including staple-like elements (tips) which are permanently deformable from a starting position in which the connector is delivered to a desired anastomosis site, to a joining position in which the staple-like elements engage the hollow structures to thereby cause the connector to connect the hollow structures where each staple-like element is attached to the annular member proximate to a center of the staple-like element and extends in a direction substantially parallel to a center line of the annular member, as recited throughout the specification and seen in the figures.

Regarding claim 40, Kaster et al. disclose that as applied to claim 1, as well as, tapering of the at least one staple portion that provides predetermined bending characteristics to the at least one staple portion, which would also depend on the deployment apparatus.

Regarding claim 41, Kaster et al. disclose that as applied to claim 40, as well as, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a C-shape in the joining position, as seen in figure 19, for example.

Regarding claim 42, Kaster et al. disclose that as applied to claim 40, as well as, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a C-shape forming a circle in the joining position, as seen in figure 19, where it is roughly a circular shape.

Regarding claim 43, Kaster et al. disclose that as applied to claim 40, as well as, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a C-shape forming overlapping circles in the joining position, as seen in figure 19 where a slight overlap is seen.

Regarding claim 46, Kaster et al. disclose that as applied to claim 1, as well as, tapering of the staple portions that is located on a radially outer side of the staple portions, as seen in figure 9. "Outer side" has not been defined with respect to the original or deployed configuration.

Regarding claim 47, Kaster et al. disclose that as applied to claim 1, as well as, tapering of each staple portion that results in a reduction of radial thickness of a part of the staple portion, relative to a radial thickness of another part of the staple portion, as recited seen in figure 9.

Regarding claim 48, Kaster et al. disclose that as applied to claim 1, as well as, tapering of each staple portion that results in a reduction of circumferential width, respectively, of another part of the staple portion, seen in the figures.

Regarding claim 49, Kaster et al. disclose that as applied to claim 1, as well as, tapering of each staple portion that results in a reduction of both a radial thickness and a circumferential width of part of the staple portion, relative to a radial thickness and a circumferential width, respectively of another part of the staple, as seen in the figures.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster et al. in US Patent No. 5,366,462 in view of Lazarus in US Patent No. 5,104,399.

Kaster et al. disclose that as applied to claim 1. However Kaster et al. do explicitly recite an annular member having sinusoidal pattern meandering about a circumferential line through the main plane of the annular member or each staple-like element that is located at an apex of the sinusoidal pattern. On the other hand, Lazarus teaches the use of a sinusoidal pattern in figure 11. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Kaster et al. to have an



annular member having a sinusoidal pattern meandering about a circumferential line through the main plain of the annular member and have each staple-like element located at an apex of the sinusoidal pattern, as taught by Lazarus for the purpose of enhancing expandability.

3. Claims 44, 45, and 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster et al. in US Patent No. 5,366,462.

Kaster et al. discloses that as applied to claims 40 and 6 as well as photo etching. Further, laser, electric erosion and electroplating are considered equivalents to etching. However, Kaster et al. do not explicitly recite tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a B-shape in the joining position, tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to an overlapping B-shape in the joining position, or a connector that is fabricated by making a two-dimensional shape from the single material and then forcing the two-dimensional shape into a three-dimensional shape. On the other hand, although not explicitly recited tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to a B-shape in the joining position and tapering of the at least one staple portion that causes the at least one staple portion to permanently deform to an overlapping B-shape in the joining position are well within the scope of the invention and obvious to one with ordinary skill in the art. An overlapping B-shape is well within the scope of the invention. Moreover, a connector that is fabricated by making a two-dimensional shape

from the single material and then forcing the two-dimensional shape into a three-dimensional shape would be an obvious method to make a tubular structure and well within the scope of the invention.

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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